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DEC 6 2005

INTERBODY INNOVATIONS

510(k) Summary

Submitter Information:

Interbody Innovations
24 Smith Road, Suite 503
Midland, TX 79705

Contact:

Todd Stanaford
Phone: 432-697-7463
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Date Prepared:

May 12, 2005

Product Name:

Classification Name: Surgical Mesh
Trade Name(s): Interbody Innovations Cement Restrictor
Panel: DCRND, Orthopedic
Classification Regulation: 21 CFR 878.3300
Product Code: JDK

Predicate Device:

This device is substantially equivalent to the following predicate devices:

Fortitude Cement Restrictor, marketed under K031837
FIDJI Large Cement Restrictor, marketed under K030871
RABEA Cement Restrictor, marketed under K020836

Interbody Innovations Cement Restrictors and predicated devices listed above, are devices that are used to occlude the medullary canal prior to the introduction of PMMA in total joint arthroplasty. None of the devices are intended for use in spine surgery. Technologically they are all virtually identical in their function and principle of operation.

Comparison to Predicates:

	PROPOSED DEVICE	FORTITUDE (K031837)	FIDJI (K030871)	RABEA (K020836)

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Intended use	Occlusion of medullar canal prior to PMMA	Occlusion of medullar canal prior to PMMA	Occlusion of medullar canal prior to PMMA	Occlusion of medullar canal prior to PMMA
Anatomical sites	Hip, knee	Hip, knee	Hip, knee	Hip, knee
Sterility	Nonsterile; to be sterilized by user	Nonsterile; to be sterilized by user	Nonsterile; to be sterilized by user	Nonsterile; to be sterilized by user
Material	PEEK-Optima (ASTM F2026)	PEEK-Optima	PEEK-Optima	PEEK-Optima
Markers	Tantalum wires (ASTM F560)	Tantalum wires	Tantalum wires	Tantalum wires

Description:

The Interbody Innovations Cement Restrictors is a hollow curved rectangular frame that is machined from extruded Polyetheretherketone (PEEK). It contains tantalum inserts that serve as location and orientation markers for radiographs. The device is intended to be used in conjunction with standard PMMA

Intended Use:

This device is intended for use in conjunction with Standard PMMA cement. The Interbody Innovations Cement Restrictors are designed to occlude the medullar canal before the introduction of PMMA, in total hip or knee replacement.

This device is not intended for use in spine applications. The safety and effectiveness have not been established when implanted into the spine.

Performance Data:

This device is constructed of the same material (polyetheretherketone, or PEEK-Optima) as the predicate device(s). This material complies with ASTM F2026. The manufacturer of this material has an FDA Device Master File, and has certified biocompatibility to ISO 10993-1 requirements for implantable contact greater than 30 days.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 6 2005

Interbody Innovations LLP
c/o Mr. Ian P. Gordon
Senior Vice President
Emergo Group, Inc.
2454 McMullen Booth Road
Suite 427
Clearwater, Florida 33759

Re: K051371
Trade/Device Name: Interbody Innovations Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: JDK
Dated: September 15, 2005
Received: September 19, 2005

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

Furthermore, the indication for use – occlusion of the medullary canal before the introduction of PMMA in total hip or knee replacement – must be prominently displayed in all labeling,

including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

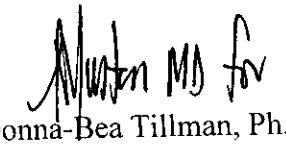
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) # (if known): K051371

Device Name: Interbody Innovations Cement Restrictor

Indications for Use:

This device is intended for use in conjunction with Standard PMMA cement. The Interbody Innovations Cement Restrictors are designed to occlude the medullar canal before the introduction of PMMA, in total hip or knee replacement.

This device is not intended for use in spine applications. The safety and effectiveness have not been established when implanted into the spine.

Prescription Use __x____ (21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
510(k) Number K051371